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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,263	04/10/2006	Motoyuki Kataoka	KATAOKA3	8893

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
STOICA, ELLY GERALD	
ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,263	KATAOKA ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. In the response to the non-final rejection of 07/26/2007, response filed on 12/26/2007, Applicant cancelled claims 1-9, amended claim 10 and added claims 11-21. Thus, claims 10-21 are pending and currently examined.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10, 20 and 21are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to a method for proliferating or regenerating renal tissue or a cell present in renal tissue by contacting G-CSF in an effective amount for said regeneration, with the renal tissue or the cell present in renal tissue, with the proviso that said regeneration is not for neutropenia and neutrophil dysfunction. This limitation is not described in the initial set of claims and is not disclosed in the specification and does not flow naturally from the subject matter described in the specification.

Consequently, this constitutes new matter and the claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim Objections

4. Claim 20 is objected to because of the following informalities: the word "necrotic" which, from the context of the subject matter of the Application is the intended word, is misspelled as "neurotic". Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 10 remains and claims 11-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shishido et al. (Nichijinshi, 33, 973-981, 1991 -cited by Applicant).

As iterated in the previous Office action, therapeutic agent's properties are inherent to its function and the activity of the agent does not stop because the use was not an intended use. Correspondingly, Shishido et al treated end-stage renal failure patients with human recombinant G-CSF and found it an effective and safe therapeutic agent for neutropenia and neutrophils dysfunction inpatients with renal failure (Abstract).

Clearly Shishido et al. teach a method of treatment of renal failure (a renal disease or nephropathy). Moreover, it is considered that end-stage renal failure is accompanied by necrosis, and thus the method of treatment of Shishido et al. inherently addresses the limitations of claims 18-21 also. Therefore, all the consequences of the G-CSF treatment were necessarily achieved and thus the claims are anticipated by Shishido et al.

On pages 6 and 7 of the Remarks, Applicant argues that Shishido et al. does not disclose any method for treatment for treating renal disease and that claim 10 relates to a method of a method for proliferating or regenerating renal tissue or a cell present in renal tissue by contacting G-CSF with the renal tissue or the cell present in renal tissue. The arguments were carefully considered but not found persuasive because, while not contending the scope of the claim 10, the broadest reasonable interpretation of the claim reads on treatment of renal tissue that is diseased. The diseased renal tissue is treated by the method of Shishido et al. as presented in the abstract and the authors gave even dosage indications (last sentence of the abstract) while clearly stating that the initial dose is for treatment of patients with renal failure. The fact is that Shishido treats the same patient as in the instant claims with the same active agent. Intention is not relevant.

7. Claim 10 remains and claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierce et al. (U.S. Pat. 6,689, 351).

Pierce et al. teach a therapeutic agent administered by the parenteral route containing recombinant proteins like G-CSF. Such parenteral administration of the

polypeptides enables the stimulation and proliferation of cell types involved in wound healing and may thus constitute appropriate treatment in such situations (col.6, lines 17-26). The type of cells present at a wound site would necessarily include types of cells that are present in the renal tissue (i.e., epithelial cells, fibroblasts, endothelial cells and blood cells). Read in the broadest reasonable interpretation, “wound" is understood as being present in a diseased tissue and the process of regenerating a tissue in a diseased organ is linked to healing the wound generated either by ischemic event or fibrotic ones. Therefore the claims are anticipated by Pierce et al.

On pages 6 and 7 of the Remarks, Applicant argues that Pierce et al. does not teach a method of treating renal disease. The arguments were carefully considered but not found persuasive because as detailed supra, the process of healing a wound would necessarily lead to treating a condition that was a consequence of that “wound” and a therapeutic agent’s properties are inherent to its function and the activity of the agent does not stop because the use was not an intended use.

8. Claim 10-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Fukuda et al. (US 20040019184).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Fukuda et al. teaches treating renal disease by administering G-CSF to patients for whom this remedy is indicated a dose is usually 0.1 to 500 μg/kg/day, preferably 1 to 50 μg/kg/day, per adult. As the frequency of dosing, G-CSF can be administered once to three times a day, for 1 to 7 days weekly. The mode of administration preferably includes intravenous administration, subcutaneous administration and intramuscular administration ([0017]; [0053]).

On page 8 of the Remarks Applicant argues that Fukuda dose not disclosed treatment of any renal disease by administration of G-CSF or that the administration has to be a combined Hepatocyte Growth Factor- G-CSF treatment. The arguments were carefully considered but not found persuasive because as shown above, Fukuda does teach treatment of renal diseases with G-CSF. Regarding the combined administration, Fukuda et al. clearly states that G-CSF and HGF can be prepared and administered as a single preparation or alternatively, they can be prepared separately, and administered on different occasions ([0057]). Further, there are no limitations in the claims to exclude combined administration.

Thus the teachings of Fukuda anticipate the claims 10--21 of the instant Application.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/ Ph.D.
Primary Examiner, Art Unit 1647